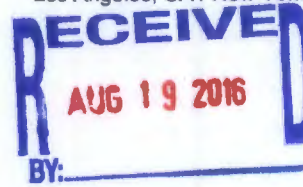


August 19, 2016

**VIA Courier and U.S. Mail**

National Freedom of Information Officer  
U.S. Environmental Protection Agency  
FOIA and Privacy Branch (2822T)  
1301 Constitution Avenue, NW  
Room 6416 West  
Washington, DC 20004  
Phone: (202) 566-1667



**Donald C. McLean**

Partner

202.857.6469 DIRECT

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**Re: Request for Information Pursuant to the Freedom of Information Act**

Dear Sir or Madam:

On behalf of our client, Dow AgroSciences LLC ("DAS"), we submit this request pursuant to the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, *et seq.* This request seeks any and all raw data underlying *The Mothers and Newborn Study of North Manhattan and South Bronx*, a federally funded epidemiology study conducted by the Columbia Children's Center for Environmental Health ("CCCEH") at Columbia University (the "Columbia Study").<sup>1</sup> EPA has relied on the Columbia Study to propose precedent-setting regulatory action with respect to the pesticide chlorpyrifos, and despite numerous FOIA requests by DAS and others to date, responsive raw data supporting the Columbia Study have not been made available.

We understand that, in response to an April 19, 2016 letter from EPA requesting the raw data, CCCEH researchers have offered to disclose to EPA "one or more data sets" (apparently, less than all of the raw data) provided they "can be properly de-identified" to ensure the privacy of the study participants. See May 18, 2016 Ltr. from L. Fried to J. Housenger, attached as Exhibit 1. Alternatively, CCCEH has offered to allow EPA staff to "review and/or re-analyze" the raw data in a "secure enclave onsite at Columbia." *Id.* Although DAS disagrees that either of the above options fulfills the Agency's and CCCEH's obligations with respect to data access and transparency in federally funded research, DAS requests that EPA promptly release any and all raw data that are being provided by CCCEH in response to the Agency's April 19 request.<sup>2</sup>

This request seeks the documents or other sources of information (*e.g.*, electronic files) containing one or more of the data elements set forth in the attached Appendix B. Please provide us with copies of the documents or the electronic files containing the raw data.

<sup>1</sup> A non-exhaustive list of relevant publications reporting results of the Columbia Study is set forth in the attached Appendix A.

<sup>2</sup> Pursuant to OMB Circular A-110, EPA has an obligation to request and make available under FOIA federally funded research data used "in developing an agency action that has the force and effect of law." By proposing a rule to revoke all tolerances for chlorpyrifos, EPA has proposed regulatory action with respect to chlorpyrifos "that has the force and effect of law." Accordingly, EPA has an obligation to request and disclose under FOIA the Columbia Study raw data.

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This request does not apply to any documents or portions thereof contained in these files that are Confidential Business Information. In addition, this FOIA request does not seek test data, manufacturing processes, or the confidential statement of formula for any pesticide product. Finally, this request does not seek any personnel, medical, or similar files subject to protection under FOIA Exemption 6, 5 U.S.C. § 552(b)(6) (2000). As noted in our prior FOIA requests, we are willing to accept the requested raw data with personal identifying information redacted or deleted, as necessary to protect the privacy interest of study participants. Specifically, as listed below in Appendix B, birth month and day are not requested. However, birth year of the children is important for purposes of replicating age-specific analyses.

The Agency is currently under a Court order to take final action with respect to a proposed rule to revoke all tolerances for chlorpyrifos by March 31, 2017. Given the time-sensitive nature of the request, we respectfully request that EPA expedite processing of this request.

We would be pleased to pay reasonable costs related to duplicating and shipping the requested information. Please contact me should it appear that the costs will exceed \$100.

If we may be of assistance with this matter, please do not hesitate to contact me at (202) 857-6469. Thank you in advance for your assistance.

Sincerely,



Donald C. McLean, Esq.



## APPENDIX A: PUBLICATIONS

- Eaton, D. L., Daroff, R. B., Autrup, H., Bridges, J., Buffler, P., Costa, L. G., Coyle, J., McKhann, G., Mobley, W. C., Nadel, L., Neubert, D., Schulte-Hermann, R., and Spencer, P. S. 2008. "Review of the toxicology of chlorpyrifos with an emphasis on human exposure and neurodevelopment," *Crit Rev Toxicol* (38 Suppl 2), pp 1-125.
- Engel, S. M., Bradman, A., Wolff, M. S., Rauh, V. A., Harley, K. G., Yang, J. H., Hoepner, L. A., Barr, D. B., Yolton, K., Vedar, M. G., Xu, Y., Hornung, R. W., Wetmur, J. G., Chen, J., Holland, N. T., Perera, F. P., Whyatt, R. M., Lanphear, B. P., and Eskenazi, B. 2016. "Prenatal Organophosphorus Pesticide Exposure and Child Neurodevelopment at 24 Months: An Analysis of Four Birth Cohorts," *Environ Health Perspect* (124:6) June.
- Factor-Litvak, P., Insel, B., Calafat, A. M., Liu, X., Perera, F., Rauh, V. A., and Whyatt, R. M. 2014. "Persistent Associations between Maternal Prenatal Exposure to Phthalates on Child IQ at Age 7 Years," *PLoS One* (9:12), p e114003.
- Lovasi, G. S., Quinn, J. W., Rauh, V. A., Perera, F. P., Andrews, H. F., Garfinkel, R., Hoepner, L., Whyatt, R., and Rundle, A. 2011. "Chlorpyrifos exposure and urban residential environment characteristics as determinants of early childhood neurodevelopment," *Am J Public Health* (101:1) Jan, pp 63-70.
- Perera, F. P., Rauh, V., Tsai, W. Y., Kinney, P., Camann, D., Barr, D., Bernert, T., Garfinkel, R., Tu, Y. H., Diaz, D., Dietrich, J., and Whyatt, R. M. 2003. "Effects of transplacental exposure to environmental pollutants on birth outcomes in a multiethnic population," *Environ Health Perspect* (111:2) Feb, pp 201-205.
- Rauh, V. A., Garfinkel, R., Perera, F. P., Andrews, H. F., Hoepner, L., Barr, D. B., Whitehead, R., Tang, D., and Whyatt, R. W. 2006. "Impact of prenatal chlorpyrifos exposure on neurodevelopment in the first 3 years of life among inner-city children," *Pediatrics* (118:6) Dec, pp e1845-1859.
- Rauh, V. A., Perera, F. P., Horton, M. K., Whyatt, R. M., Bansal, R., Hao, X., Liu, J., Barr, D. B., Slotkin, T. A., and Peterson, B. S. 2012. "Brain anomalies in children exposed prenatally to a common organophosphate pesticide," *Proc Natl Acad Sci U S A* (109:20) May 15, pp 7871-7876.
- Whyatt, R. M., Camann, D., Perera, F. P., Rauh, V. A., Tang, D., Kinney, P. L., Garfinkel, R., Andrews, H., Hoepner, L., and Barr, D. B. 2005. "Biomarkers in assessing residential insecticide exposures during pregnancy and effects on fetal growth," *Toxicol Appl Pharmacol* (206:2) Aug 7, pp 246-254.
- Whyatt, R. M., Garfinkel, R., Hoepner, L. A., Andrews, H., Holmes, D., Williams, M. K., Reyes, A., Diaz, D., Perera, F. P., Camann, D. E., and Barr, D. B. 2009. "A biomarker validation study of prenatal chlorpyrifos exposure within an inner-city cohort during pregnancy," *Environ Health Perspect* (117:4) Apr, pp 559-567.
- Whyatt, R. M., Rauh, V., Barr, D. B., Camann, D. E., Andrews, H. F., Garfinkel, R., Hoepner, L. A., Diaz, D., Dietrich, J., Reyes, A., Tang, D., Kinney, P. L., and Perera, F. P. 2004. "Prenatal insecticide exposures and birth weight and length among an urban minority cohort," *Environ Health Perspect* (112:10) Jul, pp 1125-1132.

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## APPENDIX B: DATA ELEMENTS REQUESTED

### INFANT CHARACTERISTICS

Birth weight (g)  
Head circumference (cm)  
Birth length (cm)  
Birth year  
Gestational age of newborn (wks)  
Newborn gender/infant sex  
Infant malformations  
Apgar scores  
Sex  
PON1 genotype

### MATERNAL CHARACTERISTICS

Alcohol use during pregnancy  
Breastfeeding  
Cesarean delivery (0 = no; 1 = yes)  
Community (Harlem, WH, S Bronx, etc.)  
Complications of preg and delivery  
Country of birth  
Depressive symptoms (CES-D) @ 12 mo  
Ethnicity (0 = Dominican; 1 = African American)  
ETS in the home (0 = no; 1 = yes)  
HOME score (at testing)  
Household income, annual  
Illicit drug use during pregnancy  
Language spoken in home  
Marital status  
Maternal age (yrs)  
Maternal education  
Maternal hardship  
Maternal height  
Maternal IQ  
Maternal pre-pregnancy weight  
Maternal smoking during preg  
Maternal weight gain during pregnancy (lbs)  
Medications/drugs used during preg  
Number of hours in hospital prior to delivery  
Parity (0 = nulliparous, 1 = at least one prior live birth)  
Poverty level  
PON1 genotype  
Race/ethnicity (White, AA, Hispanic, Other)  
Residential pesticide use  
Season of delivery (summer, winter, spring, fall)  
Smoking history, during pregnancy



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EXPOSURE FACTOR	Medium	Source
Cholinesterase at delivery	blood	Mother
Cholinesterase during pregnancy	blood	Mother
Cholinesterase	cord blood	Child
Butyrylcholinesterase	cord blood	Child
Butyrylcholinesterase at delivery	blood	Mother
Butyrylcholinesterase during pregnancy	blood	Mother
Chlorpyrifos at delivery	blood	Mother
Chlorpyrifos at delivery	cord blood	child
TCPy, prenatal sample 1	urine	Mother
TCPy, prenatal sample 2	urine	Mother
TCPy, prenatal sample 3	urine	Mother
TCPy, prenatal sample 4	urine	Mother
TCPy, postpartum	urine	Mother
Chlorpyrifos, week 32-34	air	Indoor
Chlorpyrifos, week 34-36	air	Indoor
Chlorpyrifos, week 36-38	air	Indoor
Chlorpyrifos, week 38-40	air	Indoor
Chlorpyrifos, postpartum	Meconium	Mother
DAP, DEP DAP, prenatal sample 1	urine	Mother
DAP, DEP DAP, prenatal sample 2	urine	Mother
TCPy, prenatal sample 2	urine	Mother
TCPy, prenatal sample 3	urine	Mother
TCPy, prenatal sample 4	urine	Mother
TCPy, postpartum	urine	MotherAdmission date/time

## CHILD HEALTH ENDPOINTS

BNBAS assessment	<= 3 days; within 5 days; <= 2 months
Baley Scales of Infant Development	6, 12 ,24, 36 months
WISC-IV intelligence test	7 years
WPPSI-III	6 years
CBCL	24 months, 3.5 years
K-CPT	5 years
ADHD	3, 3.5, 5 years
Hillside Behavioral rating scale	
NEPSY	3.5 years
PDD	3, 3.5, 5 years
MRI readings	

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